

### Remarks

The Applicants note with appreciation the Examiner's entry of the Applicants' amendment filed February 4, 2004. The Applicants further note with appreciation the Examiner's withdrawal of the rejection under 35 U.S.C. § 102. Claims 5 and 33-36 are pending in the Application.

The Applicants have amended Claims 5 and 35 to recite SEQ ID No: 6, which identifies amino acids 23-395 by its own designated sequence identifier. The SEQ ID No: 6 is contained in the sequence listing filed with the Patent office on April 2, 2001. Hence, no new matter has been presented. SEQ ID No: 6 discloses amino acids 23-395 of SEQ ID No: 1 without the corresponding polynucleotide.

The Applicants have also amended Claim 5 and 33-35 to specify that the claimed microsporidian polar tube protein is isolated. Support for this amendment can be found on page 12, line 11, and in Examples 1 and Examples 1 and 2 of the Applicants' Specification.

The Applicants have amended Claim 33 to remove the phrase "which prevents infections caused by microsporidians of species *Encephalitozoon cuniculi*."

### Claim Rejections under 35 U.S.C. § 112

Claims 33-35 have been rejected under 35 U.S.C. § 112, first paragraph, as non-enabled. The Applicants respectfully submit that, as a result of the amendment to Claim 33, the enablement rejection of these claims is now obviated. In particular, the Applicants have removed the phrase "which prevents infections caused by microsporidians of species *Encephalitozoon cuniculi*." Consequently, Claim 33 refers to a pharmaceutical composition having the protein of Claim 5 contained in a pharmaceutically acceptable carrier, without any

requirement for a particular pharmacologic effect. Support for this amendment can be found on page 14, lines 6-7 of the present specification. One skilled in the art would understand that a pharmaceutical composition, as recited in amended claim 33, refers to a composition which does not interfere with the effectiveness of any biological activity of an active ingredient, and which is not toxic to the subject to which it is administered. For example, well-known treatises that are readily available to those skilled in the art, such as Remington's Pharmaceutical Sciences, Mack Publishing Co. (A. R. Gennaro edit. 1985), indicate that a pharmaceutical composition is a composition suitable for administration to a subject that carries an active ingredient. Thus, one skilled in the art would readily appreciate that the claimed pharmaceutical composition is a composition that is suitable for administration to a host without eliciting a deleterious response, and that the phrase "pharmaceutical compositions" does not imply any pharmacologic effect of the active ingredient.

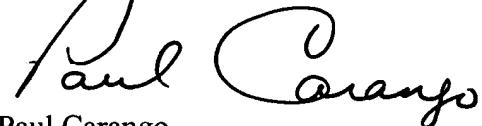
The present Specification teaches how to make and use the pharmaceutical composition of claim 33. For example, the association of the Applicants' claimed protein with a pharmaceutically acceptable vehicle is described on page 14, lines 5-7 of Applicants' Specification. It is well within the ability of one skilled in the art to formulate a pharmaceutical composition containing a protein of interest. This practice is routine in the art, again as evidenced by widely available and well-known treatises such as Remington's Pharmaceutical Services, supra. Thus, the Applicants' Specification, in combination with the knowledge of one skilled in the art, adequately teaches how to make and use the claimed pharmaceutical composition. Accordingly, the Applicants respectfully request withdrawal of the rejection of Claims 33-35 as non-enabled under 35 U.S.C. § 112, first paragraph.

**Claim Rejections Under 35 U.S.C. § 101**

Claims 5 and 33-36 have been rejected under 35 U.S.C. § 101, as allegedly being drawn to non-statutory subject matter. Claim 5 as amended now refers to an “isolated microsporidian polar tube protein.” Thus, the Applicants respectfully submit that the rejection of Claims 5 and 33-36 under 35 U.S.C. §101 is now obviated. Withdrawal of this rejection is respectfully requested.

In view of the foregoing, the Applicants respectfully submit that the Application is in condition for allowance, which is respectfully requested.

Respectfully Submitted



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